

PATENT Customer No. 22,852 Attorney Docket No. 08888.0101-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Pascale BRIAND et al.) Group Art Unit: 1631
Application No.: 09/986,797) Examiner: Not Yet Assigned
Filed: November 13, 2001 For: RECOMBINANT ADENOVIRUSES AND USE THEREOF IN GENE THEREAPY FOR TREATING EYE DISEASES	RECEIVED JUL 0 1 2003 TECH CENTER 1600/2900

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents were previously submitted in prior applications, Application No. 09/087,156, filed May 28, 1998, which is a continuation of Application No. 08/513,998, filed October 27, 1995, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120.

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U.S. Application No. 09/986,797 Attorney Docket No. 08888.0101-02

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: June 30, 2003

By: Charles D. Niebylski

Reg. No. 46,1(16

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U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,641,749	06/24/97	Yan et al.			
	5,641,750	06/24/97	Louis		DE	CEIVED
	5,667,968	09/16/97	La Vail et al.		1111	OLIVED
	5,672,344	09/30/97	Kelley et al.		JUL	0 1 2003
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	FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No	
···	WO 91/15580	10/17/91	Fung et al.				
	WO 92/05272	04/02/92	Bredesen				
	WO 92/17211	10/15/92	Wagner et al.				
	WO 90/02551	03/22/94	Berlinger et al.				
	WO 96/13276	05/09/96	Cuthbertson				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Breakfield et al., "Herpes Simplex Virus for Gene Delivery to Neurons, New Biologist 3:203-218, (1991).
Stramm et al., "B-Glurcuronidase Mediated Pathway Essential for Retinal Pigment Epithelial Degradation of Glysocaminoglycans. Disease Expression and In Vitro Disease Correction Using Retroviral Mediate cDNA Transfer, Experimental Eye Research 50:521-32, (1990).
Le Gal La Salle <i>et al.</i> , "An Adenovirus Vector for Gene Transfer into Neurons and Glia in the Brain, Science 259:988-90, (1993).

Examiner		Date Considered
*Examiner:	ner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw lithrough citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
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OMB No. 0651-0011

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	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Stratford-Perricaudet et al., "Feasibility of Adenovirus-Mediated Gene Transfer in Vivo," Bone Marrow Trans. 9:151-152, (1992). Stratford-Perricaudet et al., "Gene Transfer into Animals: The Promise of Adenovirus," Human Gene Transfer 219:51-61, (1991). Marshal, "Gene Therapy's Growing Pains," Science 269:1050-55, (1995).
	Stratford-Perricaudet et al., "Gene Transfer into Animals: The Promise of Adenovirus," Human Gene Transfer 219:51-61, (1991).
•	Marshal, "Gene Therapy's Growing Pains," Science 269:1050-55, (1995).
	Culver et al., "Gene Therapy for Cancer," Trends in Genetics 10:174-78, (1994).
	Miller et al., "Targeted Vectors for Gene Therapy," FASEB J. 9:190-99, (1995).
	Hodgson, "Advances in Vector Systems for Gene Therapy," Exp. Opin. Ther. Patents 5:459-468, (1995).
	Bookstein et al., "Suppression of Tumorigenicity of Human Prostate Carcinoma Cells by Replacing a Mutated RB Gene," Science 247:712-15, (1990).
	Wills et al., "Adenovirus Vector for Gene Therapy of Cancer," J. Cell BioChem supp. 17E-17F:204, 5216, (1993).
	Maneval et al., "Tumor Suppressor Gene Therapy of Cancer: Adenoviral Mediated Gene Transfer of p53 and Retinoblastoma cDNA into Human Tumor Cell Lines," J. Cell Biochem. Supp. 18C:204, N524, (1994).
	Rosenfeld <i>et al.</i> , "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium," Cell 68:143-55, (1992).
	Huang et al., "Suppression of the Neoplastic Phenotype by Replacement of the RB Gene in Human Cancer Cells," Science 242:1563-66 (1988).
	Friedmann "Gene Therapy of Cancer Through Restoration of Tumor-Suppressor Functions?," Cancer 70:1810-1817, (1992).
	Neve, "Adenovirus Vectors Enter the Brain," Trends in NeuroSci., 16:251-53, (1993).
	Orkin et al., "Report & Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy, US NIH 1-41 (1995).
	Bennett et al., "Photoreceptor Cell Rescue in Retinal Degeneration (rd) Mice by in Vivo Gene Therapy," Nature Medicine 2:649-654 (1996).
Examiner	Date Considered
*Examiner:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

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riling Date	November 13, 2001 Group. 1031
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Turner et al., "A Common Progenitor for Neurons and Glia Persists in Rat Retina Late in Development," Nature 328:131-136, (1987).
	Strieter et al., "Interleukin-8, A Corneal Factor That Induces Neovascularization," American Journal of Pathology 141:1279-1284 (1992).
	Seabra et al., "Retinal Degeneration in Choroidermia: Deficiency of Rab Geranylgeranyl Transferase," Science 259:377-381 (1993).
	Dryia et al., "A Point Mutation of the Rhodospin Gene in one Form of Retinitis Pigmentosa," Nature 343:364-366 (1990).
	Farrar et al., "A Three-base-pair Deletion in the Peripherin-RDS Gene in one Form of Retinitis Pigmentosa," Nature 354:478-480 (1991).
	Cremers et al., "Cloning of a Gene That is Rearranged in Patients with Choroideraemia," Nature 347:674-677 (1990).
	Faktorovich et al., "Photoreceptor Degeneration in Inherited Retinal Dystrophy Delayed by Basic Fibroblast Growth Factor," Nature 347:83-86 (1990).
	Shoffner et al., "Spontaneous Kearns-Sayre/Chronic External Opthalmoplegia Plus Syndrome Associated with a Mitochondrial DNA Deletion: A Slip-replication Model and Metabolic Therapy," Proc. Natl. Acad. Sci., USA. 86:7952-7956 (1989).
	Bowes <i>et al.</i> , "Isolation of Candidate cDNA for the Gene Causing Retinal Degeneration in the rd Mouse," Proc. Natl. Acad. Sci. USA 86:9722-9726 (1989).
	Lem et al., "Retinal Degeneration is Rescued in Transgenic rd Mice by Expression of the cGMP Phosphodiesterase Beta Subunit," Proc. Natl, Acad. Sci., USA, 89:4422-4426 (1992).
	La Vail et al., "Multiple Growth Factors, Cytokines, and Neurotrophins Rescue Photoreceptor from the Damaging Effects of Constant Light," Proc. Natl. Acad. Sci. USA, 89:11249-11253 (1992).
	Bajocchi <i>et al.</i> , "Direct in Vivo Gene Transfer to Ependymal Cells in the Central Nervous System Using Recombinant Adenovirus Vectors," Nature Genetics 3:229-234 (1993).
	Li et al., "Inherited Retinal Dystrophy in the RCS Rat: Prevention of Photoreceptor Degeneration by Pigment Epithelial Cell Transplantation," Exp. Eye Res., 47:911-917 (1988).
	Turner et al., "Lineage-independent Determination of Cell Type in the Embryonic Mouse Retina," Neuron 4:833-845 (1990).
	Davidson et al., "A Model System for in vivo Gene Transfer into the Central Nervous System Using an Adenoviral Vector," Nature Genetics 3:219-223 (1993).
Examiner	Date Considered
*Examiner:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Akli et al., "Transfer of a Foreign Gene into the Brain Using Adenovirus Vectors," Nature Genetics 3:224-228 (1993).
Akaki et al., "A Deletionin the Ornithine Aminotransferease Gene in Gyrate Atrophy," Journal of Biological Chemistry 267:12950-12954 (1992).
Anderson et al., "Gene Transfer into Mammalian Central Nervous System Using Herpes Virus Vectors: Extended Expression of Bacterial lacZ in Neurons Using the Neuron-Specific Enolase Promoter," Human Gene Therapy 3:487-499 (1992).
Pepose et al., "Herpes Simplex Viral Vectors for Therapeutic Gene Delivery to Ocular Tissues. Recent Breakthroughs in the Molecular Genetics of Ocular Diseases," Investigative Ophthalmology & Visual Science 35:2662-2666 (1994).
Bok, "Retinal Transplantation and Gene Therapy. Present Realities and Future Possibilities," Investigative Ophthalmology & Visual Science 34:473-476 (1993).
Li et al., "In Vivo Transfer of a Reporter Gene to the Retina Mediated by an Adenoviral Vector," Investigative Ophthalmology & Visual Science 35:2543-2549 (1994).
Bennett et al., "Adenovirus Vector-Mediated in Vivo Gene Transfer into Adult Murine Retina," Investigative Ophthalmology & Visual Science 35:2543-2594
Berger <i>et al.</i> , "Mutations in the Candidate Gene for Norrie Disease," Human Molecular Genetics 1:461-462 (1992).
Howell et al., "Leber Hereditary Optic Neuropathy: Involvement of the Mitochondrial ND1 Gene and Evidence for an Intragenic Suppressor Mutation," Am. J. Hum. Genet. 48:935-942 (1991).
Giebel et al., "Tyrosinase Gene Mutations Associated with Type IB ('Yellow') Oculocutaneous Albinism," Am. J. Hum. Genet. 48:1159-1167 (1991).
Hotta et al., "Expression of Human Ornithine Aminotransferase (OAT) in Oat-Deficient Chinese Hamster Ovary Cells and Fibroblasts of Gyrate Atrophy Patient," Jpn. J. Opthalmol. 36:28-32 (1992).

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